K122476

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Ansell

Traditional 510(k)
Ansell Healthcare Products, LLC

510(k) SUMMARY

Applicant:	Ansell Healthcare Products, LLC 1635 Industrial Road Dothan, AL 36303, USA Phone: (334) 615-2563 Fax: (334) 615-2574
Contact Person:	Robert Mahler, Regulatory Affairs Director, Americas
Date Prepared:	January 28, 2012
510(k) Number:	K122476
Proprietary Name:	LifeStyles® Smooth™ 2-in-1 Massage & Lubricant
Common Name:	Personal Lubricant
Classification Name:	Lubricant, patient, vaginal, latex compatible (Class II, 21 CFR 884.5300, Product Code NUC)
Predicate Device:	Durex Play™ Temptations Assorted Lubricants (K060098)

Device Description:
LifeStyles® Smooth™ 2-in-1 Massage & Lubricant is a non-sterile, water-based personal lubricant designed to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The formula is a non-staining, non-sticky, biocompatible gel-like liquid, with a strawberry aroma, that is compatible with natural rubber latex, polyurethane, and polyisoprene condoms. The product is provided in a plastic pump dispenser

Indications for Use:
LifeStyles® Smooth™ 2-in-1 Massage & Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Technological Characteristics:
LifeStyles® Smooth™ 2-in-1 Massage & Lubricant contains a similar blend of water and water soluble ingredients as the predicate device. Testing per ASTM D7661 indicated that, like the predicate, the lubricant formulation is compatible with condoms. As with the predicate, testing for cytotoxicity, vaginal irritation, sensitization, and systemic toxicity in accordance with ISO 10993 indicated device biocompatibility. Bench testing indicated that the lubricant is non-staining and that it has an appropriate viscosity, pH, specific gravity, appearance, color and odor for substantial equivalence to the predicate. USP testing for Total Aerobic Microbial Counts, Total Yeast and Mold Counts, absence of microbial pathogens, and antimicrobial effectiveness indicated microbial quality. The osmolality of the device was tested. Real-time and accelerated aging tests indicate a 3 year shelf-life for the lubricant.

Summary:
LifeStyles® Smooth™ 2-in-1 Massage & Lubricant has the same intended use and basic technological characteristics as the predicate device. This lubricant is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

Ansell Healthcare Products, LLC
% Ms. Donna Di Gangi
Principal Consultant
DiGangi Consulting
4 Los Verdes Drive
SAN LUIS OBISPO CA 93401

Re: K122476
Trade/Device Name: LifeStyles® Smooth™ 2-in-1 Massage & Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 29, 2013
Received: February 1, 2013

Dear Ms. Di Gangi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122476

Device Name: LifeStyles® Smooth™ 2-in-1 Massage & Lubricant

Indications for Use: LifeStyles® Smooth™ 2-in-1 Massage & Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122476